Quality Systems Workshop Goals and Objectives

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Introduction

This document lists the overall workshop goals and the learning objectives for each of the workshop modules. At the conclusion of the workshop participants should be able to accomplish the objectives listed below.

Goals

The overall goals of this workshop are to:

1. describe the framework of a laboratory quality system
2. provide information on how to address the essential elements of a quality system, such as organizational responsibilities, specimen management, personnel management, quality control, documentation and record-keeping, equipment management, and external quality assessment.
3. discuss how to identify and fill gaps in a quality system
4. present a forum to exchange experiences in efforts to establish quality systems
5. provide guidance on how to implement quality system essentials in L1 and L2 testing sites

Overview of Quality Systems

Objectives include:

1. Define Quality Assurance, Quality Control, and Quality System;
2. Compare & Contrast the NCCLS and ISO Quality System model;
3. List essential components of a Quality Systems program;
4. Summarize key issues addressed by each quality system essential;
5. Identify references that can serve as guidance for developing a laboratory Quality Assurance program.

Organizational responsibilities

Objective include:

1. Recognize the importance of management commitment to the success of a quality plan;
2. Identify resources needed for implementing a quality system;
3. Summarize the basics of developing a Quality Manual;
4. Identify factors that contribute to the successful implementation of a Quality System.

Documents and records

Objective include:

1. Provide a rationale for maintaining laboratory records;
2. Develop examples of record-keeping forms;
3. Describe the process of document preparation and control;
4. Determine important records to keep for testing, personnel and quality control;
5. Assist laboratory staff in use of records to locate sources of error;
6. Outline a plan for developing Standard Operating Procedures.

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Quality Systems Workshop Goals and Objectives, Continued

Equipment management

Objectives include:
1. Describe at least three reasons for developing an equipment management program;
2. Outline a method to use to validate the proper functioning of a new piece of equipment;
3. Describe factors to consider when selecting new equipment for the laboratory;
4. Implement an equipment maintenance program.

Purchasing and inventory

Objectives include:
1. Relate the importance of an inventory control system with quality laboratory testing;
2. Recommend strategies for implementing an effective inventory control program.

Specimen management

Objectives include:
1. Describe the impact specimen management has on patient care;
2. Develop a laboratory handbook;
3. Provide adequate documentation of procedures needed to insure proper collection and transport of different types of specimens;
4. Develop a specimen requisition form that includes all required information;
5. Provide a rationale for rejecting unsatisfactory specimens;
6. Explain the necessity of tracking specimens;
7. Develop a policy for storing specimens.

Analytic process control-quality control

Objectives include:
1. Describe a method to verify that a new batch of blood agar plates is acceptable for use;
2. Describe procedures to check the validity of stains, and regents;
3. Suggest procedures for monitoring susceptibility results;
4. Describe quality control for infectious disease serology test;
5. Differentiate between calibrators and controls;
6. Calculate the mean and standard deviation of a set of quantitative data;
7. Given Levey-Jennings charts containing plots of different levels of control sera, identify days when patient specimens should not be reported due to “out-of-control” results.

Assessments: external and internal

Objectives include:
1. Describe the difference between internal quality control and external quality assessment;
2. Discuss the importance of an EQA program in improving the quality of laboratory test results;
3. Describe at least three EQA methods;
4. Name the most frequent laboratory errors identified in EQA reports;
5. Outline a method to investigate an unacceptable test result from an EQA specimen.
6. Discuss the importance of conducting an audit;
7. Plan for and conduct an internal audit;
8. Differentiate between corrective actions and preventive actions;
9. Implement a corrective and preventive action program.

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Quality Systems Workshop Goals and Objectives, Continued

Personnel

Objectives include:
1. Define competency assessment;
2. Establish a program to verify competency of employees;
3. List items that should be included in personnel records;
4. Identify potential sources of employee performance problems;
5. Implement a continuing education program.

How to be and effective trainer

Objectives include:
1. Recognize the many roles of a trainer;
2. Describe how to overcome training anxieties;
3. Summarize the process for developing a training program;
4. Utilize a model facilitators' guide to conduct another training program.

Facilities and safety

Objectives include:
1. List the principles of biosafety;
2. Describe the four biosafety levels;
3. Describe safety equipment;
4. Identify references for safety information.